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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,639	06/28/2005	Jason Fong	50164/015002	3127

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EXAMINER	
GRAFFEO, MICHEL	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/517,639	FONG ET AL.	
	Examiner	Art Unit	
	Michel Graffeo	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 33-51 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 33-51 is/are rejected.

7)☒ Claim(s) 33,43,44,49 and 50 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Action

The preliminary Amendment (Filed December 9, 204.) canceled claims 1-32 and presented new claims 33-51. Claims 33-51 are pending and examined.

Claim Objections

Claims 33 and 49-50 are objected to because of the following informalities: claim 33 contains a typo "§" and claims 49 and 50 recite the "method" of claim 46 which is itself a composition claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43-44 and 49-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "low" in claims 43-44 and 49-50 is a relative term which renders the claim indefinite. The term "low" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 33-38, 40-51 rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,073,922 to Wyburn-Mason in view of ADAP Drugs: http://www.aegis.com/factshts/network/access/drugs/clot.html Last modified 26 June 1996. Retrieved 9 November 2005 and further in view of PDR ® Electronic Library http://www.thomsonhc.com/pdrel/librarian/ND_PR/Pdr/SBK/2/PFPUI/Ao4T53O11Yyld7/ND_PG/SearchBreadCrumbPrintReady/ND_CP/Pdr/CS/C24210/ND_CPR/KeywordSearch/ND_T/PDRel/ND_P/PdrStedmanHerbal/DUPLICATIONSHIELDSYNC/67663A/ND_B/PDRel/PFFormActionId_pdrcommon.BrandAction/null/SBK/2?ContentDesc=Hydrocor

tone+Tablets&DocumentDefinition=pdrcommon.Pdr&DocumentId=52401914 Issued November 2001. Retrieved 9 November 2005.

Wyburn-Mason teach a method of treating rheumatoid arthritis (in current claim 1; see Abstract) with a compound such as clotrimazole (in current claims 37-38, 45, 51; see Abstract and col 5 lines 30-31) comprising a pharmaceutically acceptable carrier (in current claims 46, 51; see col 6 lines 50-53) and further teaches that cortisone and corticosteroids have been commonly used in treating rheumatoid arthritis (in current claims 33, 40-42, 45-46, 51; see col 1 lines 38-41).

Wyburn-Mason does not teach a method wherein the azole and steroid are administered 24 hours apart or 14 days apart for example, nor does Wyburn-Mason recite the specific corticosteroids applicant claims or the low dosage claimed.

http://www.aegis.com/factshts/network/access/drugs/clot.html teaches that clotrimazole is sold as 10mg lozenges (in current claims 43-44 and 47-50; see Dosage) and the PDR teaches that hydrocortisone is supplied in 10mg dosages (in current claims 44 and 47-48, 50 see page 1 of 1).

One of ordinary skill in the art would have appreciated and been able to see from the teaching in Wyburn-Mason that glucocorticoid or mineralocorticoid would have been an obvious corticosteroid particularly because Wyburn-Mason teach that there are a plurality of corticosteroids that are used as rheumatoid arthritis treatments (see col 1 lines 40-41: "Chemical compounds which have been commonly used in treating rheumatoid arthritis are corticosteroids,...")

One of ordinary skill in the art would have appreciated the use of both an azole, such as clotrimazole, and a steroid, such as a corticosteroid, since both have been traditionally used to treat rheumatoid arthritis. That the azole and corticosteroid are used separately is not a patentable feature of the claim since people suffering from rheumatoid arthritis have been using both treatments separately for example if one treatment fails or the condition is not ameliorated with only one treatment. One of ordinary skill in the art would also appreciate the obviousness of combining two treatments for the same indication wherein the treatments have a different mechanism of action thereby treating the indication via separate pathways such that the treatment has more than an additive affect on a patient. Further, combining agents which are known to be useful to treat rheumatoid arthritis individually into a singe composition useful for the very same purpose is prima facie obvious. See In re Kerkhoven 205 USPQ 1069. Since it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining an azole and a steroid flows logically from their having been individually taught in the prior art.

One of ordinary skill in the art would have been motivated to combine the above references and as combined would teach the invention as claimed. One of ordinary skill in the art would have been motivated to combine Wyburn-Mason with the PDR and ADAP since the PDR and ADAP are provided to show the current state of the art at the time the application was filed as well as the dosage availability of the compositions. Specifically, the PDR is a reference document for physicians and is commonly used to

show the current availabilities of pharmaceuticals on the market and that ADAP is another resource guide for pharmaceuticals. Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Claims 33-51 rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,073,922 to Wyburn-Mason in view of ADAP Drugs: http://www.aegis.com/factshts/network/access/drugs/clot.html Retrieved 9 November 2005 as applied to claims 33-38 and 40-51 above and further in view of PDR ® Electronic Library http://www.thomsonhc.com/pdrel/librarian/ND_PR/Pdr/SBK/2/PFPUI/Ao4T53O11Yyld7/ND_PG/SearchBreadCrumbPrintReady/ND_CP/Pdr/CS/C24210/ND_CPR/KeywordSearch/ND_T/PDRel/ND_P/PdrStedmanHerbal/DUPLICATIONSHIELDSYNC/67663A/ND_B/PDRel/PFFormActionId_pdrcommon.BrandAction/null/SBK/2?ContentDesc=Hydrocortone+Tablets&DocumentDefinition=pdrcommon.Pdr&DocumentId=52401914 Retrieved 9 November 2005 as applied to claims 33-38 and 40-51 above and further in view of US Patent No. 6,545028 to Jensen et al.

Jensen et al. teach the treatment of inflammatory disorders such as rheumatoid arthritis (in current claim 39; see col 13 line 5) with a triazole such as fluconazole (in current claim 39; see col 7 lines 45-60).

One of ordinary skill in the art would have been motivated to combine the above references and as combined would teach the invention as claimed. One of ordinary skill in the art would have been motivated to combine the above references with Jensen et

al. because Jensen et al. is cited by Wyburn-Mason. Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9 November 2005
MG

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